

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Investigating the Impact of Mandala Coloring on Anxiety in Patients with COVID-19: A Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of mandala staining on the anxiety of patients with COVID-19

Design

This research project is a randomized, controlled, double-blind, blind clinical trial with two parallel arms. They are randomly divided into intervention and control groups.

And will be followed up for 6 days.

Settings and conduct

The study will be conducted in the wards of hospitalized patients with covid19 in Amir Al-Momenin Hospital. Studying on both sides will be double-blind. The intervention group included patients with Covid 19 who underwent Mandala staining for 6 consecutive days and 30 minutes each day. The control group included patients with Covid 19 who received only routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 15 to 60 years Have mild to moderate anxiety Stability of hemodynamic status
Exclusion criteria: Lack of willingness to continue participating in the study Patient discharge

Intervention groups

Intervention group: In this way, patients complete The State-Trait Anxiety Inventory -Spielberger questionnaire before starting the intervention, and then after 6 consecutive sessions of Mandala staining daily and every 30 minutes, The State-Trait Anxiety Inventory - Spielberger questionnaire is completed again and their anxiety is measured. Control group: In this group, patients do not receive any intervention from the researcher and only receive routine care.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039711N6**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **prospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Mohamad Golitaleb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

Email address

m.golitaleb@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-19, 1399/04/29

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of Mandala Coloring on Anxiety in Patients with COVID-19: A Randomized Clinical Trial

Public title

Effect of mandala staining on anxiety in patients with

COVID-19

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age 15 to 60 years Have mild to moderate anxiety
Stability of hemodynamic status
Exclusion criteria:
Lack of willingness to continue participating in the study
Patient discharge

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into intervention and control groups. Sixty patients were randomly assigned to either the intervention or control groups, initially 6 blocks of 10 different T and C letters (which represent the intervention and control groups) (30) from the intervention group and 30 from the intervention group. People belong to the control group). Then, the blocks were randomly selected to obtain a 60-sided combination of blocks. It opens to tell which group the patient falls into.

Blinding (investigator's opinion)
Double blinded

Blinding description
Clinical caregivers, data analysts, and patients are not aware of being in the control or intervention group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Deputy of Education and Research,Campus University of Medical Sciences site,Basij square,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.ARAKMU.REC.1399.089

Health conditions studied

1

Description of health condition studied

Covid 19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Anxiety

Timepoint

At the beginning of the study and 6 days after the intervention

Method of measurement

The State-Trait Anxiety Inventory -Spielberger

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The researcher will use Mandala staining to investigate its effect on the anxiety of patients with hospitalized Covid-19. In this way, patients complete The State-Trait Anxiety Inventory -Spielberger questionnaire before starting the intervention, and then after 6 consecutive sessions of Mandala staining daily and every 30 minutes, The State-Trait Anxiety Inventory -Spielberger questionnaire is completed again and their anxiety is measured.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital
Full name of responsible person
Fatemeh Khademi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. alireza kamali
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Grant name

Arak University of Medical Sciences

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source
100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohamad Golitaleb
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Shared data including demographic and disease information, type and method of intervention, information about sleep quality of participants before and after intervention.

When the data will become available and for how long

Start the access period 6 months after the results are published.

To whom data/document is available

Researchers and people working in nursing education as well as nursing clinical staff.

Under which criteria data/document could be used

The data can be used for education, research and clinical nursing. The applicant must be in the nursing field The data applicant only uses data for teaching, research and clinical nursing.

From where data/document is obtainable

Mohamad golitaleb, Department of critical care nursing, school of nursing, Arak university of medical sciences E mail: Mohamadgolitaleb@gmail.com
Tel: +989379366279

What processes are involved for a request to access data/document

After ensuring that the data applicant is in the nursing field, we will be immediately responded to the request form by email.

Comments